



DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the Defense Production Act of 1950; Review of Plans of Action

AGENCY: Antitrust Division, U.S. Department of Justice.

ACTION: Notice of review.

SUMMARY: Notice is hereby given pursuant to section 708 of the Defense Production Act of 1950 (“DPA”) for the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID-19 (“Medical Devices Plan of Action”), the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID-19 (“Medical Gases Plan of Action”), the Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID-19 (“Diagnostic Test Kits Plan of Action”), and the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID-19 (“Drug Products Plan of Action”) proposed by the Federal Emergency Management Agency (“FEMA”), that the Acting Assistant Attorney General finds for each that the purposes of section 708(c)(1) of the DPA may not reasonably be achieved through a plan of action having less anticompetitive effects or without any plan of action. Given these findings, the Medical Devices Plan of Action, the Medical Gases Plan of Action, the Diagnostic Test Kits Plan of Action, and the Drug Products Plan of Action may become effective following the publication of this notice. Given these findings, the Medical Devices Plan of Action, the Medical Gases Plan of Action, the Diagnostic Test Kits Plan of Action, and the Drug Products Plan of Action may become effective following the publication of this notice.

SUPPLEMENTARY INFORMATION: Under the DPA, FEMA may enter into plans with representatives of private industry for the purpose of improving the efficiency with which private firms contribute to the national defense when conditions exist that may pose a direct threat to the national defense or its preparedness. Such arrangements are generally known as “voluntary agreements.” Participants in an existing voluntary agreement may adopt documented methods, known as “plans of action,” to implement that voluntary agreement. A defense to actions brought under the antitrust laws is available to each participant acting within the scope of a voluntary agreement and plan of action that has come into force under the DPA.

The DPA requires that each proposed plan of action be reviewed by the Attorney General prior to becoming effective. If, after consulting with the Chair of the Federal Trade Commission, the Attorney General finds that the purposes of the DPA’s plans of action provision “may not reasonably be achieved through a . . . plan of action having less anticompetitive effects or without any . . . plan of action,” the plan of action may become effective. 50 U.S.C. 4558(f)(1)(B). All functions which the Attorney General is required or authorized to perform by section 708 of the DPA have been delegated to the Assistant Attorney General, Antitrust Division. 28 CFR. 0.40(l).

On August 17, 2020, the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (“Voluntary Agreement”) became effective. The proposed Medical Devices Plan of Action, the proposed Medical Gases Plan of Action, the proposed Diagnostic Test Kits Plan of Action, and the proposed Drug Products Plan of Action contain documented methods to implement the Voluntary Agreement as summarized below:

1. The Medical Devices Plan of Action creates a mechanism to immediately meet exigent Medical Device requests anywhere in the Nation and to ensure that actions to support Medical Device stockpiling and reserves do not interfere with immediate

requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Device recipients. This mechanism involves the establishment several Sub-Committees organized by medical device type, which are designed to foster a close working relationship among FEMA, the Department of Health and Human Services (“HHS”), and participants in the Sub-Committees to address national defense needs through cooperative action under the direction and active supervision of FEMA. The proposed Medical Devices Plan of Action includes terms, conditions, and procedures under which participants agree voluntarily to participate in the Sub-Committees.

2. The Medical Gases Plan of Action creates a mechanism to immediately meet exigent Medical Gas requests anywhere in the Nation and to ensure that actions to support Medical Gas stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Gas recipients. This mechanism involves the establishment several Sub-Committees organized by medical gas type, which are designed to foster a close working relationship among FEMA, HHS, and participants in the Sub-Committees to address national defense needs through cooperative action under the direction and active supervision of FEMA. The proposed Medical Gases Plan of Action includes terms, conditions, and procedures under which participants agree voluntarily to participate in the Sub-Committees.
3. The Diagnostic Test Kits Plan of Action creates a mechanism to immediately meet exigent requests for Diagnostic Test Kits and other Testing Components anywhere in the Nation and to ensure that actions to support stockpiling of Diagnostic Test Kits and other Testing Components do not interfere with immediate requirements. This mechanism involves the establishment several Sub-Committees organized by testing kit methodology, testing kit supplies, and testing kit components, which are designed

to foster a close working relationship among FEMA, HHS, and participants in the Sub-Committees to address national defense needs through cooperative action under the direction and active supervision of FEMA. The proposed Diagnostic Test Kits Plan of Action includes terms, conditions, and procedures under which participants agree voluntarily to participate in the Sub-Committees.

4. The Drug Products Plan of Action creates a mechanism to immediately meet exigent requests for Drug Products, Drug Substances, and Associated Medical Devices anywhere in the Nation and to ensure that actions to support Drug Products, Drug Substances, and Associated Medical Devices stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential recipients of Drug Products, Drug Substances, and Associated Medical Devices. This mechanism involves the establishment several Sub-Committees organized by drug products and drug substances, development of new treatments, as well as domestic industrial base expansion, which are designed to foster a close working relationship among FEMA, HHS, and participants in the Sub-Committees to address national defense needs through cooperative action under the direction and active supervision of FEMA. The proposed Drug Products Plan of Action includes terms, conditions, and procedures under which participants agree voluntarily to participate in the Sub-Committees.

FEMA has certified that the proposed Medical Devices Plan of Action, the proposed Medical Gases Plan of Action, the proposed Diagnostic Test Kits Plan of Action, and the proposed Drug Products Plan of Action are each necessary to provide for the national defense in the event of a pandemic.

FEMA requested that the Acting Assistant Attorney General, Antitrust Division, issue a finding that the proposed Medical Devices Plan of Action, the proposed Medical Gases Plan of Action, the proposed Diagnostic Test Kits Plan of Action, and the proposed

Drug Products Plan of Action each satisfies the statutory criteria set forth in 50 U.S.C. 4558(f)(1)(B). The Acting Assistant Attorney General, Antitrust Division, reviewed the proposed Medical Devices Plan of Action, the proposed Medical Gases Plan of Action, the proposed Diagnostic Test Kits Plan of Action, and the proposed Drug Products Plan of Action and consulted on them with the Acting Chairwoman of the Federal Trade Commission. On May 7, 2021, by letter to Deanne Criswell, FEMA Administrator, Richard Powers, Acting Assistant Attorney General, Antitrust Division, issued findings, pursuant to 50 U.S.C. 4558(f)(1)(B), that the purposes of the DPA's plan of action provision "may not reasonably be achieved through a . . . plan of action having less anticompetitive effects or without any . . . plan of action" for the following plans of action:

1. Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID-19;
2. Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID-19;
3. Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID-19; and
4. Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID-19.

David G. B. Lawrence,

Chief, Competition Policy & Advocacy Section.

[FR Doc. 2021-10874 Filed: 5/21/2021 8:45 am; Publication Date: 5/24/2021]